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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,717	01/28/2002	Douglas William Hamilton	7250-11	8819

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EXAMINER

KOSSON, ROSANNE

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/889,717

Applicant(s)

HAMILTON ET AL.

Examiner

Rosanne Kosson

Art Unit

1653

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED on September 22, 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-14, 16-19 and 21-23.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see below.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: PTO-892 and reference attached.


ROBERT A. WAX
PRIMARY EXAMINER

In view of Applicants amendments, the rejection of claim 23 under 35 USC 112, 2d paragraph is withdrawn.

The rejection of all the claims under 35 USC 103 is maintained, however, as Applicants arguments are not persuasive. Applicants assert that their invention is not obvious because Curtis et al. do not disclose culturing cells on fibers, and fibers are solid cylinders, not hollow cylinders, or tubes. In reply, the rejection is the combination of the teachings of Curtis et al. and the University of Strathclyde. Curtis et al. disclose culturing cells on tubular forms that contain channels that are the same as Applicants' channels. The channels may be on the outside or on the inside of the tubes. The purpose of the channels, as disclosed by Curtis et al., Tokyo University and Hitachi Chemical Co. Ltd., is to provide increased area for cell growth and a way of orienting cell growth in the case of neurons. Strathclyde discloses that high surface area may be provided by culturing cells on fiber bundles, that different types of fibers may be used to deliver and remove reagents, thereby improving the efficiency of each, and that the fibers may be stacked in layers to form scaffolds for larger cultures. Fibers are not novel to Applicants. As noted previously, it would have been obvious to one of ordinary skill in the art to combine the features of each reference- tubular shapes with channels or cylindrical shapes with channels, bundled or stacked together- in a method of culturing cells for the advantages disclosed by each reference.

Regarding the hollow fiber cell culture technique of Strathclyde, the cells do attach to the fibers. These are not suspension cultures. Measuring the number of cells per unit volume does not necessarily mean that the cells are in suspension. The number of cells per unit volume is determined periodically to provide an indication of cell growth over time. A small portion of the contents may be removed from the bioreactor and thoroughly mixed to suspend the cells so that the cell density may be measured. Strathclyde is not explicit on the point of cell attachment, but see the enclosed information brochure from FiberCell Systems, Inc. (Hollow Fiber Cell Culture Technology).

Regarding Hansbrough et al., it is clear in the previous Office action that this reference was cited not for its teaching of channels but for its teaching that cells may be cultured on fiber frameworks containing cell growth factors. As for skin dressings, Applicants claims are not limited as to whether or not the cell culture method is external or internal to a subject.

Applicants additionally assert that their multi-layer matrices provide for three-dimensional cell growth, while the tubular substrates of Curtis et al. create barriers to cell growth. In reply, Curtis et al. disclose that their substrates may be formed into a wide variety of shapes and arrangements and may be made of biodegradable materials. Tubular forms aligned along an axis or bundled together do not create a barrier to cell growth, particularly if they made of a biodegradable material.

Applicants have not shown that their claimed method produces unexpected results compared to the methods of Curtis et al. or Strathclyde.

In view of the foregoing, Applicants have not distinguished their invention over the prior art, and the claims are not in condition for allowance.